

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

SHERRY L. JONES
Plaintiff

VS.

BLACKSTONE MEDICAL, INC., \$
SCT, INC., DISANTO TECHNOLOGY, \$
INC., AND SSI DIVESTURE, INC., \$
D/B/A MEDSOURCE TECHNOLOGIES \$
Defendants \$

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CAUSE NO. 6:07CV455

JURY DEMAND

**PLAINTIFF'S RESPONSE TO SEPARATE DEFENDANT
SCT, INC.'S MOTION TO DISMISS**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW Sherry L. Jones, (“Plaintiff”), who files this her Response to Separate Defendant SCT, Inc.’s Motion to Dismiss, the Plaintiff would respectfully show unto the Court as follows:

I.
BACKGROUND FACTS

On or about October 17, 2002, Sherry Jones had surgery on her neck to implant the 3° Anterior Cervical Plating System, which is part of the Blackstone Cervical System. Documents produced by Blackstone Medical, Inc. (“Blackstone”) in this case indicate that Blackstone designed the product at issue and created specifications for manufacturers of component parts to follow. The product implanted into Plaintiff contained component parts manufactured by SCT, Inc. (“Defendant SCT”) and SSI Divesture, Inc. d/b/a MedSource Technologies (“Defendant MedSource”). In 2006, medical testing revealed that the screws

manufactured by SCT, Inc. and marketed by Blackstone were fractured, causing Plaintiff to have a choking sensation and risk of paralysis. On May 8, 2008, Plaintiff had surgery to remove the hardware from her neck due to complications with the same. During the course of discovery, it was also discovered that the top locking plate manufactured by SSI Divesture, Inc. d/b/a MedSource Technologies fractured. It is unclear at this time whether SCT, Inc. and/or SSI Divesture, Inc. d/b/a MedSource Technologies complied with the specifications provided to them for manufacture of the component parts. Defendant SCT has participated in the lawsuit since February 2008.

II.

SCT, INC.'S MOTION TO DISMISS

SCT, Inc. requests that this Court dismiss it from the present lawsuit under the Biomaterials Access Assurance Act. Defendant SCT claims that as a raw materials and component parts supplier, it has a right to be dismissed from the present lawsuit. Defendant SCT cites various provisions of the BAAA in support of its Motion to Dismiss, but failed to refer the Court to important provisions regarding the biomaterials suppliers that the statute was intended to protect and the limited discovery that the Court is permitted to allow prior to ruling on the motion to dismiss. Many, if not all, of the arguments raised by SCT have already been raised by Disanto and addressed by the Court. However, since these arguments have been raised again, Sherry Jones feels compelled to reiterate her previous position in order to preserve her arguments as to SCT.

III.

LEGAL BACKGROUND

Congress determined that it was necessary to protect raw materials and component part manufacturers from lawsuits in certain situations. A reasonable reading of Congress'

Findings suggests that the Biomaterials Access Assurance Act was enacted to protect suppliers of raw materials and component parts that “are not designed or manufactured specifically for use in medical devices.” 21 U.S.C. § 1601(3)(B).

Assuming the BAAA is applicable in this case, it still allows for the imposition of liability on the biomaterials suppliers if there is evidence that its component parts failed to meet applicable contractual requirements and/or specifications. 21 U.S.C. § 1605(a)(3); see also, 21 U.S.C. § 1604(d). Further, when a defendant seeks the protections of the BAAA through a Motion to Dismiss, the Court may permit discovery limited to the issues that are directly relevant to the Motion to Dismiss. 21 U.S.C. § 1605(c)(1)(B)(i). Specifically in this case, the Court may allow limited discovery into the issue of whether or not Defendant SCT’s component parts (screws) failed to adhere to the contractual requirements/specifications as established by Blackstone.

IV. ARGUMENT

(a) SCT, Inc. is not protected under the BAAA.

Congress’ *Findings*, as contained in §1601 of the BAAA, indicates that the BAAA is meant to protect those suppliers of parts that are not designed or manufactured specifically for use in medical devices. In other words, this statute was designed to protect manufacturers who produce parts and/or materials and sell them on the open market with no knowledge or control as to how those parts and/or materials are later utilized or in which products the parts and/or materials are later placed. This makes sense in that a supplier of raw materials or component parts who places their product on the market for general use has little or no control over how their material/product is later manipulated and/or

incorporated into subsequent products. The potential profit for selling bulk biomaterials and parts in this manner would be too low to justify the almost unlimited risk, thereby justifying the limits on their liability as necessary to assure a proper supply of said raw materials and products.

However, Defendant SCT intentionally manufactured its “screws” for use in a specific medical device - Blackstone’s 3° Anterior Cervical Plating System. To this end, Defendant SCT and Blackstone entered into an agreement for the production of the screws specifically for placement in Blackstone’s cervical plate system. In short, Defendant SCT manufactured this component part specifically for use in a medical device, and not to sell it on the open market for use in implants generally. Defendant SCT maintained 100% control over the manufacturing of its product and the subsequent implantation of it into the Blackstone Cervical Plate System. Accordingly, the protections of this statute should not be afforded to Defendant SCT in this situation. Given the wording of this provision and Congress’ *Findings*, component parts that were intended to be covered under the BAAA were component parts that are not specifically manufactured for use in a specific medical device. Therefore, Defendant SCT should not be afforded protection under the BAAA and Defendant SCT’s motion to dismiss should be denied.

(b) Defendant SCT did not meet contractual requirements and/or specifications.

Blackstone Medical, Inc. has claimed that SCT, Inc., the supplier of the screws in the product at issue, did not comply with contractual specifications/requirements in the manufacture of the screws. A metallurgist is being consulted by Plaintiff in order to confirm that the component parts did not meet the specifications as identified and required by Blackstone. At this time, the metallurgist has not been able to perform conclusive testing

that would confirm or deny compliance with contractual specifications. It is anticipated that the appropriate testing will be conducted over the next few weeks once Defendant MedSource makes an appearance and has an opportunity to inspect the device at issue.

(c) Discovery should be allowed on issues related to the Motion to Dismiss.

Alternatively, and at the very least, this Court should permit Plaintiff to continue its investigation into whether the component part suppliers complied with contractual specifications as provided by Blackstone Medical, Inc. If evidence exists to suggest that they failed to adhere to these contractual specifications and requirements, then the protections of the BAAA should not be afforded Defendant SCT.

The BAAA appears to be a statute meant to protect raw material and component part suppliers from the high cost of litigation. At this time, it appears that there is not a need for further written discovery in order to determine the issues related to the Motion to Dismiss unless Defendant SCT has documents in its possession that it feels are relevant to the issue. All blueprints, purchase orders for parts, and contracts between Blackstone and Defendant SCT appear to have been produced by the parties throughout the course of litigation to date. It is anticipated that the process to determine whether Defendant SCT complied with specifications should be resolved once Defendant MedSource appears and the parties have determined a mutually agreeable time for everyone to be present for destructive testing in order to determine several issues, including whether the biomaterials suppliers complied with specifications. Should Defendant SCT be dismissed prior to this testing, and should the testing reveal that Defendant SCT failed to comply with specifications, neither Plaintiff nor Defendant Blackstone would be able to implead Defendant SCT back into the present case until a final judgment of the Court. 21 U.S.C.

§ 1606(a). Therefore, Plaintiff requests that this Court permit discovery into the issues related to the Motion to Dismiss prior to ruling on the Motion to Dismiss.

IV.
PRAYER

WHEREFORE, PREMISES CONSIDERED Plaintiff prays that this Court enter an order denying Defendant Defendant SCT's Motion to Dismiss, or, in the alternative, an order permitting limited discovery into the subject matter of the Motion to Dismiss.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that on this 15th day of December, 2008, a true and correct copy of the above and foregoing Plaintiff's Response to Separate Defendant SCT, Inc.'s Motion to Dismiss has been delivered to the attorneys listed below by electronic filing notification:

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